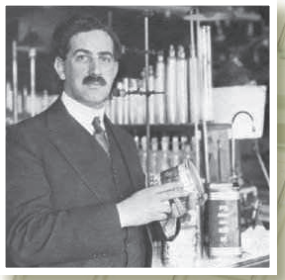
Food and Drug Administration
Center for Food Safety and Applied Nutrition

100 *Years*



Working to Keep Food and Cosmetics Safe and Promote Good Nutrition

The "Poison Squad"

A Bit of History . . .

On a sweltering June day in 1906, President Theodore Roosevelt signed the historic ***Pure Food and Drugs Act*** *into law. Thus began a* ***public health mission*** *that remains on the cutting edge of* ***science, nutrition,*** *and regulatory* ***risk management*** *a century later.*

Today, FDA's ***Center for Food Safety and Applied Nutrition*** *continues this mission . . . regulating U.S. foods and cosmetics for the sole purpose of* ***keeping you safe.***

FDA came about when, by 1906, product safety in the U.S. had reached crisis proportions.

Shocking disclosures of unsanitary conditions in processing plants . . . the use of poisonous preservatives and dyes in foods . . . and "cure-all" claims for worthless and dangerous medicines were the reality. They also provided key inspiration for two American public health heroes:

Harvey Wiley

Dr. Harvey Wiley was the lead chemist at the scientific branch of the U.S. Department of Agriculture — then known as the "Division of Chemistry." He had been steadily building an influential coalition of health experts and scientists (referred to as the "Poison Squad"), lobbying for legislation to protect consumers from unsafe products.

President Teddy Roosevelt had been pressuring Congress to enact a pure food bill. The Senate agreed — but the House of Representatives was hesitant. Finally, Roosevelt called in the Speaker of the House and insisted that the bill be brought to the floor.

As Roosevelt made his demands, Wiley energized his coalition for a last burst of pressure. Committees met . . . and agreements were made. The Pure Food and Drugs Act became law (the first nationwide consumer protection law). . . and the Bureau of Chemistry was given regulatory authority to support their scientific mission.

Food and Drug Administration
College Park, MD

And with that, the early iteration of the Food and Drug Administration was born.

FDA: The What, Who and How

Imagine not knowing if you were putting your family at serious risk with the food you brought home from the market . . . or if your shampoo contained ingredients with dangerous side effects.

Or what if a disease-preventing immunization wasn't worth the risks . . . or if an X-ray could cause you more harm than good? FDA's century-long role in promoting public health has had an impact on the life of every American for the last 100 years. Today, FDA continues to keep you and your family safe in many ways — some very familiar, and some that may actually surprise you.

FDA: An Agency within Health and Human Services

As part of the U.S. Department of Health and Human Services, FDA strives to provide round-the-clock public health protection across the U.S. And although the name, size and even the physical location of FDA have changed over the years, the core mission has not.

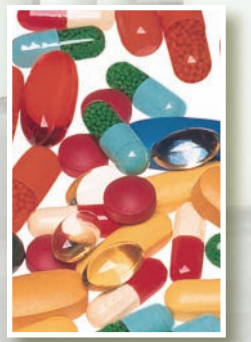
As a public health agency, FDA enforces the present-day **Federal Food, Drug, and Cosmetic Act**, which evolved from the original Pure Food and Drugs Act of 1906, and incorporated as well a number of other laws Congress had enacted over the years.

- As a whole, FDA's jurisdiction reaches from your local **blood bank** to the **feed** provided to livestock . . . from your **microwave oven** to your **flu shot** . . . from the **moisturizer** you apply each morning to the farm-fresh **produce** you put in your dinner salad.
- Within FDA, the **Center for Food Safety and Applied Nutrition** (CFSAN) regulates 80% of our food (everything except meat products, poultry products, and certain egg products, which are regulated by the United States Department of Agriculture/USDA), as well as cosmetics.

Did You Know?

FDA Regulates All:

- **Foods** (except raw meat and poultry and certain processed egg products)
- **Cosmetics**
- **Animal drugs** and **feed**
- Prescription and non-prescription **drugs**
- **Blood products, vaccines**, and **tissues for transplantation**
- **Medical equipment**
- **Devices that emit radiation** — including microwave ovens



FDA's Impact . . . and CFSAN's Mission

As an agency, FDA has wide-reaching impact on the safety of Americans. FDA personnel can be found all across the county . . . and FDA regulates a sizable portion of the products you purchase every day.

- FDA employs **1,100 investigators and inspectors**, covering the country's almost 95,000 FDA-regulated businesses. FDA is nearby with offices in **157 cities** across the country.
- FDA ensures the safety of a **trillion dollars' worth** of products in the U.S. That's nearly one-fourth of the total consumer expenditures of U.S. citizens.
- Under FDA's watch, about **3,000 products** a year are found to be unfit for consumers and are withdrawn by voluntary recall or court-ordered seizure.
- FDA checks more than 30% of all imported shipments into the U.S. (roughly **10 million shipments annually**), and **30,000 import shipments a year** are detained at the port of entry due to goods that appear to be unacceptable.
- All told, the products FDA regulates account for about 25 cents of every dollar consumers spend.
- FDA protects every American at the bargain rate of **2 cents per day.**

Mission Statement . . .

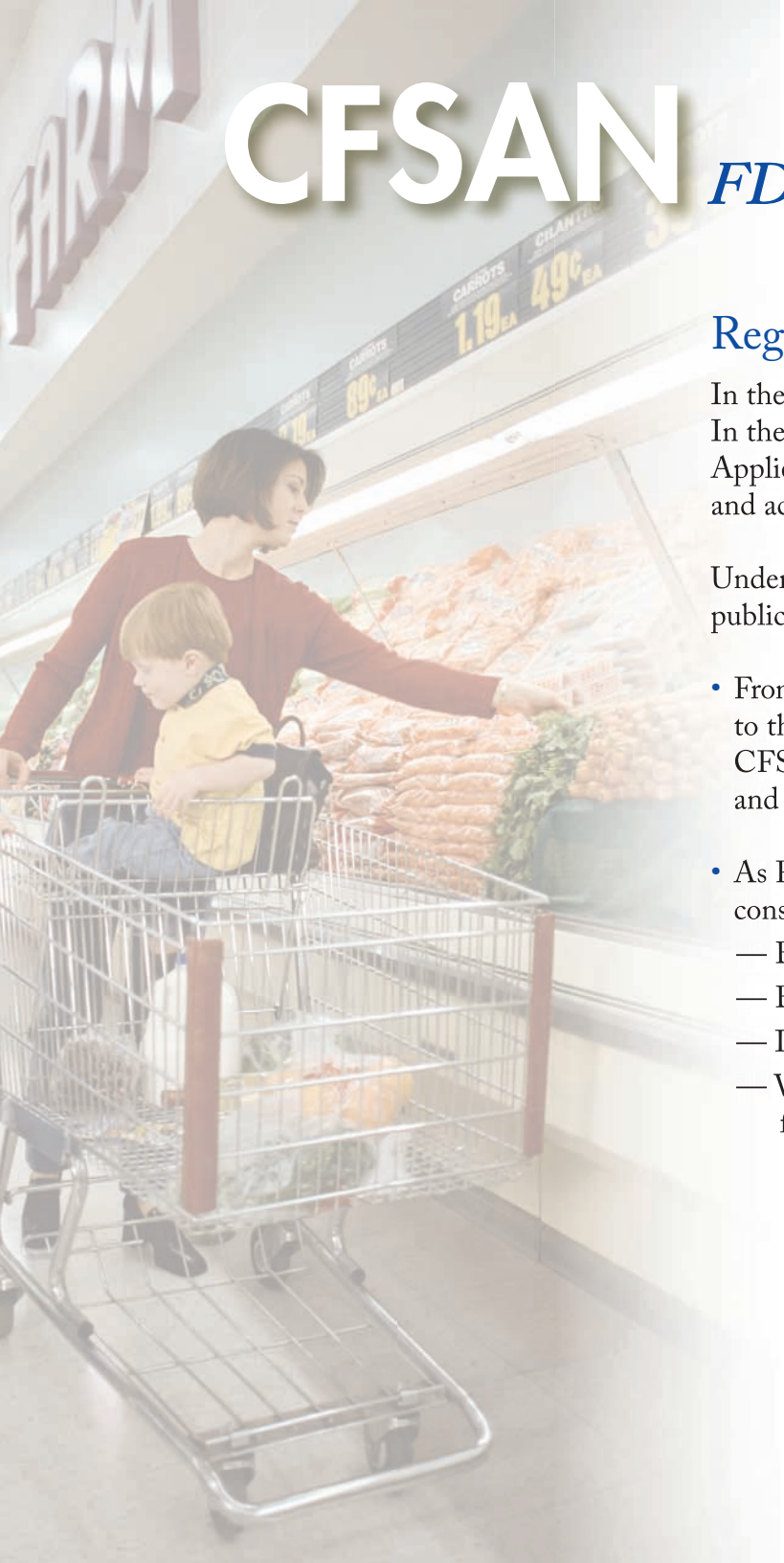
FDA: With You at Every Meal

As FDA celebrates its 100th anniversary, the agency continues to evaluate and regulate the multitude of products for which it has pledged responsibility. You can receive donated blood with confidence . . . use cosmetic products with assurance . . . and know that the medicines you take have been reviewed by skilled scientists, and testing is completed in the best-equipped laboratories available.

But for the American consumer, nowhere is FDA's presence more important than for the food you eat every day. At the supermarket . . . in the kitchen . . . and on the dinner table, perhaps the greatest and most familiar way FDA influences everyday lives — and health — is by making sure the U.S. food supply is among the safest and most nutritious in the world.

This critical responsibility is handled by **FDA's Center for Food Safety and Applied Nutrition.**

The Center for Food Safety and Applied Nutrition *(CFSAN), in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.*



CFSAN *FDA's Center for Food Safety and Applied Nutrition*

Regulating the U.S. Food Supply

In the United States, the safety of the food supply is something most consumers take for granted. In the century since the Pure Food and Drugs Act was passed, FDA's Center for Food Safety and Applied Nutrition (CFSAN) has worked to ensure that food in the U.S. is safe, sanitary, wholesome, and accurately labeled, and that cosmetics are safe and properly labeled.

Under this mandate, CFSAN has become a world leader in the promotion and protection of public health.

- From the first food color regulations in 1907 . . . through the nutrition labeling standards of 1990 . . . to the current bioterrorism preparedness and response rules and nutrition information initiatives, CFSAN has been conducting critical and innovative work in food and cosmetic safety, labeling, and quality standards.

- As FDA enters its second century, CFSAN continues to meet its responsibilities of protecting consumers by:
  - — Educating and informing the public
  - — Evaluating new and innovative technologies
  - — Integrating science and law
  - — Working cooperatively with state, local, and international governments to enhance food safety and improve nutrition

CFSAN Regulates Imported Food, Too

In today's marketplace — both worldwide and at your own neighborhood grocery store — there is more food available than ever before. Technology — such as advances in refrigeration and global transportation — has made this possible. Fish from around the world is flown fresh daily to all corners of the country . . . fruits and vegetables that are out of season in the U.S. are available year-round . . . and exotic herbs and other non-native foods help us enjoy ethnic flavors from across the globe.

But how do we know these foods are safe?

The fact is, even though these foods are imported, they still fall under the watchful eye of CFSAN. In fact, 65 percent of all imports arriving at the 350 ports of entry to the U.S. each year are food. Regardless of where the food originates, it is still considered part of the U.S. food supply — and thus becomes CFSAN's responsibility.

In addition, CFSAN works with international organizations like the World Health Organization (WHO), the Food and Agricultural Organization (FAO), and the Codex Alimentarius Commission. CFSAN scientists and policy makers work directly with foreign governments to ensure their understanding of U.S. requirements and to ensure that the level of international food standards meets consumer and regulatory needs.

Regulating the U.S. Food Supply: Big Responsibility . . . and Big Dollars

Nationwide, the Center for Food Safety and Applied Nutrition regulates:

- $240 billion worth of domestic food
- $15 billion worth of imported foods
- $15 billion worth of cosmetics sold across state lines

For consumers, that means that CFSAN is working hard to make sure the food in your grocery cart each week is properly labeled, wholesome — and, most of all, safe.

Understanding CFSAN

The Faces of CFSAN

The Center has over 800 employees — ranging from administrators to highly specialized professionals, most of them in CFSAN's primary headquarters and research facility just outside Washington, D.C. in nearby College Park, Maryland. Each plays a specific role in enabling CFSAN to continue its ongoing mission.

These experts include:

- Chemists
- Microbiologists
- Physicians
- Toxicologists
- Food Technologists
- Pathologists
- Molecular Biologists
- Pharmacologists
- Nutritionists
- Epidemiologists
- Mathematicians
- Sanitarians
- Public Health Educators
- Consumer Safety Officers
- Lawyers
- Administrative Professionals

What They Do . . . and How They Do It

American consumers spend 25 cents of every consumer dollar on products that are regulated by FDA. Of this amount, approximately **75 percent is spent on food.** That means CFSAN is regulating products that have a tremendous dollar value in the United States.

Keeping Food Safe and Secure . . . from the Farm to the Table

CFSAN regulates the safety and security of the U.S. food supply from the products' point of processing (or entry into the U.S.) all the way to the point of sale. In other words, CFSAN follows food "from the farm to the table."

Overall, this extensive "regulatory route" covers:

- Approximately 130,000 U.S. food facilities, like food manufacturers, processors and packers, and food warehouses
- About 3,500 cosmetic firms

FDA Support at State and Local Levels

In addition to Federal regulation, there are also hundreds of thousands of local food establishments and outlets that are regulated by state and local authorities.

These include:

- 600,000 restaurants and institutional food service operations
- 235,000 supermarkets, grocery stores, and other food outlets

To help state and local authorities maintain high levels of food safety within these establishments, FDA provides guidance, model codes, training, and other technical assistance.

Did You Know?

The Center for Food Safety and Applied Nutrition regulates **cosmetics**, too!

CFSAN regulates:

- All cosmetics once they have been released in the marketplace
- Any color additives that are used in formulating cosmetics
- All cosmetic labeling

Facts

- A "cosmetic" is defined as a product intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions.
- Cosmetics include skin-care creams, lotions, powders and sprays, perfumes, lipsticks, fingernail polishes, eye and facial makeup, permanent waves, hair colors, deodorants, baby products, bath oils, bubble baths, and mouthwashes, and any material intended for use as a *component* of a cosmetic product.

CFSAN *How They Do It*

CFSAN's Top Tasks

There's no doubt that CFSAN's role in keeping the food supply safe and secure is a significant one. The Center's primary responsibilities include:

- Safety of substances added to food — like flavor and color **additives**
- Safety of foods and ingredients developed through **biotechnology**
- Hazard Analysis and other Critical Control Point **(HACCP)** regulations — a high-tech approach aimed at identifying and preventing potential food safety problems *before* they happen
- Scientific assessment of claims made about **nutritional properties** of foods
- Regulatory and research programs to address health risks associated with foodborne **chemical** and **biological contaminants**
- Regulations and activities dealing with the **proper labeling** of foods and cosmetics
- Regulations and policy governing the safety of **dietary supplements, infant formulas,** and **medical foods**
- Food industry **surveillance** and **compliance**
- Consumer **education** and industry **outreach**
- Cooperative programs with **state and local governments**
- **International** and safety harmonization efforts

How They Do It: The CFSAN Method

Everyone knows that to get the job done right, you need the right tools. CFSAN accomplishes its mission and tasks using these methods:

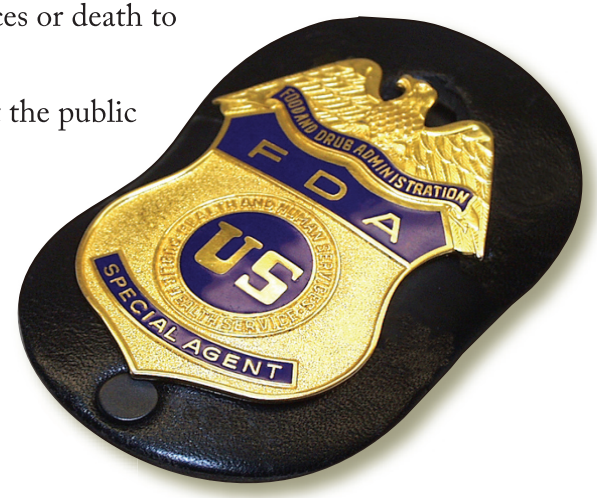
- Practical public policies to ensure safe, nutritious food
- Inspection of establishments
- Collection and analysis of samples
- Monitoring of imports
- Premarket review (e.g., of food and color additives)
- Notification programs (e.g., companies notify the agency that they plan to market a new infant formula, or make a major change in the formulation or processing of existing infant formula products)
- Regulations/agreements (e.g., memoranda of understanding)
- Evidence-based scientific evaluations of health claims
- Consumer surveys, focus groups
- Laboratory research
  - — Develop/improve methods for detecting pathogens and chemical contaminants in food
  - — Determine health effects of food contaminants
  - — Determine effects of processing on food composition
  - — Determine health effects of dietary factors
  - — Investigate factors that contribute to virulence of biological contaminants
- Pilot plant for food processing and packaging and biotechnology studies
- Cooperative activities/technical assistance
- Collection and analysis of information
- Stakeholder awareness and participation through outreach and public meetings
- Public information and education on cosmetic and food safety, nutrition and other Center activities

What Happens When a Product Is Unsafe?

In the everyday lives of consumers, much of what is going on at FDA is not typically on the radar screen. Consumers are not aware of every drug and color additive evaluated, or each food sample that is tested. But knowing that these practices continue every day at FDA, one does have to wonder: What happens if a product *is* deemed unsafe by FDA?

As the regulator of all new products under its authority, FDA prevents unsafe ones from ever coming to market. But FDA remains vigilant, checking products and ingredients that are *already* in the marketplace. So, if a product is for sale in the marketplace and found later to be unsafe, FDA will act and may take a number of steps.

- In order to **remove a food from commerce** when the agency has a reasonable belief the food may present a serious health threat, FDA can **access the records** that manufacturers/producers, distributors, transporters, and others in the food industry must establish and maintain to identify the sources of all food and food ingredients received and to whom all food was released.
- **Administratively detain** a food for which the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.
- Request a **voluntary recall** by the manufacturer/producer to protect the public from an unsafe product.
- Obtain a **court order** to:
  — Force a company to stop selling a product, and/or
  — Have products already produced seized and destroyed.
- When warranted, **criminal penalties** — including prison sentences — are sought against manufacturers and distributors.



CFSAN *Partnering for Success*

Who Plays a Role?

While CFSAN's mission is to protect and promote public health, that responsibility is shared with others. Although this has always been true, the demands and complexities of today's society make it more apparent now than ever. Key players in successful food safety practices include:

- Other government agencies
- Industry
- Academia
- Healthcare providers and educators
- Consumers

To this end, the Center has established formal collaborative endeavors, such as:

- **The Joint Institute for Food Safety and Applied Nutrition** (JIFSAN): Established between FDA and the University of Maryland (UM) in April 1996, the Institute is a jointly administered, multidisciplinary research and education program and includes research components from CFSAN, the Center for Veterinary Medicine (CVM), and UM.
- **The National Center for Food Safety and Technology** (NCFST) is, with the Illinois Institute of Technology, a government/academia/industry collaboration that yields critical information that enhances the ongoing efforts to ensure the safety of food.
- **University of Mississippi: Natural Products Research Center** works with CFSAN to improve the quality and safety of dietary supplements.

Prevention through Education:

Consumers are part of the success story too.

CFSAN's role has evolved over the years to include extensive, hands-on food safety and nutrition education programs for consumers — including children, older Americans, people with weakened immune systems, and pregnant women. Education is critical — because consumers are the "final link" in the food chain that runs from the farm to the table.

- Over the years, FDA's education campaigns have kept pace with burgeoning new technology, scientific advances, new risks and potential pathogens, and types of foods being offered to U.S. consumers.
- The agency continues to inform consumers about safe food handling and preparation, and gives them the information they need to prepare healthy, nutritious meals for themselves and their families.

CFSAN: Creating Modern Multimedia Campaigns

Recent education programs include:

- *Food Safety for Moms-to-Be*
- *Preventing Listeriosis in Pregnant Hispanic Women in the U.S.*
- *Science and Our Food Supply*

CFSAN's Four Keys to Food Safety Success *Leveraging • Collaboration • Cooperation • Partnering*

FDA's Center for Food Safety and Applied Nutrition Partners

CFSAN works with such partners as USDA in overseeing and regulating all aspects of the food supply.

Government Partners Include:

U.S. Department of Agriculture
- — Food Safety and Inspection Service
- — Cooperative State Research, Education, and Extension Service
- — National Agricultural Library
- — Food and Nutrition Service

USDA/FDA Foodborne Illness Education Information Center

U.S. Environmental Protection Agency

U.S. Department of Homeland Security
- — Customs and Border Protection

U.S. Department of Commerce's National Marine Fisheries Service, National Oceanic and Atmospheric Administration

U.S. Department of the Treasury
- — Alcohol and Tobacco Tax and Trade Bureau

U.S. Department of Justice

Federal Trade Commission

State and Local Governments

International Partners:

Codex Alimentarius Commission — An international food standard-setting organization of the **Food and Agriculture Organization** (FAO) and the **World Health Organization** (WHO)

Foreign Governments — To help establish internationally recognized safety standards, and rules and regulations for imported foods.

CFSAN *Looking Ahead*

Public Health . . . Growing Trends

The food industry and the technologies used in food production and packaging are constantly evolving. And, although the U.S. food supply is among the world's safest, new trends in food production, transportation, storage, and consumption have brought with them new public health concerns.

CFSAN continues to consider the effects of increased demand for fresh foods . . . foods traveling long distances . . . Americans eating outside the home more frequently . . . and new kinds of food contaminants. What's more, *sources* of food contamination are almost as numerous and varied as the contaminants *themselves*. These include everything from pre-harvest conditions to contamination introduced during processing, packaging, transportation, or preparation.

And so, CFSAN enters its next hundred years with its focus on five principal areas:

- Food Defense
- Food Safety
- Nutrition
- Dietary Supplements
- Cosmetic Safety

CFSAN in Action

In addition to staying on the cutting edge of science and regulatory responsibilities related to these ever-evolving concerns, CFSAN continues to consider how other societal and regulatory trends will impact their mission today and for the future:

- **Obesity.** This growing crisis is associated with increased risk of serious illness and death. With accurate and useful food labeling being a key CFSAN objective, the Center will be looking at ways to enhance the food label. In addition, CFSAN will increase consumer education efforts toward reducing obesity and overweight, and increasing health and nutrition overall.
- **Continued Food Safety Efforts.** With more foods from more sources, CFSAN will continue to monitor the food supply to ensure safe standards.
- **Ensuring that genetically modified foods are safe.**
- **Good manufacturing practices for dietary supplements.** This will ensure that consumers are protected from products that are not pure or don't contain what is claimed on the label.
- **Food Allergen Labeling.** All domestically manufactured and imported packaged food products that were labeled on or after January 1, 2006, are required to identify in plain English any ingredient that is, or contains protein from, any of the eight major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, or soybeans. CFSAN is working on standards for use of the term "gluten-free" on food labels and will continue to monitor emerging food allergen issues.
- **Working with industry to enhance food safety systems for preventing food terrorism and enabling rapid response and containment.** Overall, these proactive prevention efforts will also prepare CFSAN to respond to new food safety issues as they arise.

CFSAN *Prepared and Responsive*

Security and Preparedness: FDA's **Rules**

FDA's Public Health Security and Bioterrorism Preparedness and Response Act of 2002 Rules include very specific requirements to help ensure the safety of the U.S. food supply.

Here's a summary of those rules — and how they impact industry:

- ***Registration of Food Facilities*** **Final Rule**
  Requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with FDA.
- ***Prior Notice of Imported Food*** **Interim Final Rule**
  Requires that FDA receive advance notice of all imported food before it arrives in the U.S. to enable FDA to determine which shipments should be inspected upon arrival.
- ***Establishment and Maintenance of Records*** **Final Rule**
  Requires persons in the U.S. that manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of all food received or released.
- ***Administrative Detention*** **Final Rule**
  Establishes procedures that FDA would use to administratively detain food when FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.

Current Areas of Food Safety Concern

Looking forward, CFSAN continues to explore such issues as:

- Nutrient concerns (folic acid fortification, pediatric iron toxicity)
- Dietary components (*trans* fat and cholesterol)
- Biological pathogens (bacteria, viruses, parasites)
- Naturally occurring toxins (mycotoxins, ciguatera toxin)
- Chemical contaminants, including pesticide residues
- Toxic metals (lead and mercury)
- Decomposition and foreign objects (glass; insect or rodent infestation)
- Food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans)
- Radionuclides (radioactive elements that can accidentally contaminate food)
- Animal-based TSE-type diseases (BSE, chronic wasting disease)
- Food additive and food contact substance safety
- Biotechnology-derived product safety
- Product tampering
- Cosmetic adverse reactions

CFSAN *Snapshot of Food Safety Milestones*

1906
Pure Food and Drugs Act is passed by Congress.

1907
First **Certified Color Regulations** are issued at the request of manufacturers and consumers, listing seven colors found suitable for use in foods.

1927
The Bureau of Chemistry becomes two separate entities. Regulatory functions: **Food, Drug, and Insecticide Administration**; nonregulatory research: **Bureau of Chemistry and Soils**.

1930
The name of the Food, Drug, and Insecticide Administration is shortened to **Food and Drug Administration (FDA)**.

1938
The Federal Food, Drug, and Cosmetic (FDC) Act is passed by Congress to replace obsolete act from 1906.

1939
First Food Standards are issued for canned tomatoes, tomato purée, and tomato paste.

1949
FDA publishes **Guidance to Industry** for the first time. This guidance, "Procedures for the Appraisal of the Toxicity of Chemicals in Food," will come to be known as the "black book."

1952
FDA Consumer Consultants are appointed in each field district to communicate with consumers.

1954
First large-scale **Radiology Examination of Food** is carried out by FDA on imported tuna suspected of being radioactive following atomic blasts in the Pacific.

1958
FDA publishes in the Federal Register the first list of **Substances Generally Recognized As Safe (GRAS)**. The list contains nearly 200 substances.

1959
U.S. Cranberry Crop is recalled three weeks before Thanksgiving; FDA conducts tests to check for aminotriazole, a weed killer found to cause cancer in laboratory animals.

1969
FDA begins administering **Sanitation Programs** for milk, shellfish, food service, and interstate travel facilities, and for preventing poisoning and accidents.

1973
Low-Acid Food Processing regulations are issued after botulism outbreaks from canned foods.

1980
Infant Formula Act establishes special FDA controls to ensure necessary nutritional content and safety.

Over the years, there have been many milestones at FDA. Notable advances in consumer protection typically happen in response to dangerous/bad situations that require action to make a "change for the better."

Many of these milestones have occurred in the area of food safety. In each case, FDA/CFSAN stepped in to fulfill its public health mission of keeping the U.S. food supply among the safest and most nutritious in the world.

1990

Nutrition Labeling and Education Act requires *all* packaged foods to bear nutrition labeling and all health claims for foods to be consistent with terms defined by the Secretary of Health and Human Services.

1994

Dietary Supplement Health and Education Act establishes specific labeling requirements and authorizes FDA to proclaim good manufacturing practice regulations for dietary supplements.

1998

FDA requires a **warning label on unpasteurized juice** stating that the juice may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

2000

FDA requires that a **safe handling statement** for shell eggs be put on egg cartons to help prevent disease from *Salmonella* Enteritidis.

2001

FDA issues a **consumer advisory**: "How to Safely Handle Refrigerated Ready-to-Eat Food and Avoid Listeriosis" for pregnant women, older adults, and people with weakened immune systems.

2003-2004

FDA issues **Public Health Security and Bioterrorism Preparedness and Response Act of 2002 Rules**.

2004

FDA and EPA issue a consumer advisory: "What You Need to Know About Mercury in Fish and Shellfish for Women Who Might Become Pregnant, Women Who Are Pregnant, Nursing Mothers, and Young Children," providing advice on how to get the positive health benefits from eating fish and shellfish while minimizing exposure to any harmful effects from mercury.

2006

Food Allergen Labeling and Consumer Protection Act goes into effect, requiring that all ingredients derived from eight allergenic foods be described on food labels with the name of the allergenic food.

100 Years and Moving Forward

Center for Food Safety and Applied Nutrition

Working to Keep Food and Cosmetics Safe and Promote Good Nutrition

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Department of Health and Human Services

For more information, visit:
www.cfsan.fda.gov

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